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510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

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1) Submitter name, address, contact

Boehringer Mannheim Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 845-2327

Contact Person: John D. Stevens

Date Prepared: April 17, 1996

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2) Device name

Proprietary name: Elecsys 2010® analyzer

Common name: immunoassay analyzer

Classification name: Discrete photometric analyzer for clinical use

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3) Predicate device

We claim substantial equivalence to the Boehringer Mannheim ES300 Immunoassay system.

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4) Device Description

The Elecsys 2010 analyzer is a fully automated, random access, computer controlled analytical system for quantitative and qualitative determinations of analytes in body fluids

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5) Intended use

The Elecsys 2010 analyzer is intended to be used for the in vitro quantitative and qualitative analysis of analytes in body fluids.

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510(k) Summary Elecsys® 2010 Analyzer, Continued

6) Comparison to predicate device

The Boehringer Mannheim Elecsys 2010 analyzer is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed ES300 Immunoassay analyzer.

The following table compares the Elecsys 2010 with the predicate device. Specific data on the performance of the system have been incorporated into the draft labeling in attachment 5. Labeling for the predicate device in provided in attachment 6.

Similarities:

Feature	Elecsys 2010 Analyzer	ES300 Analyzer
Intended use	Intended for the in vitro quantitative/qualitative determination of analytes in body fluids	Same
Number of reagents	Up to 2	Same
Sample detection	Liquid level detection and clot detection	Same
Sample type	Serum and plasma	Same
Host interface	RS232C bidirectional	Same

Differences:

Feature	Elecsys 2010 analyzer	ES300 analyzer
Operating principle	Electrochemiluminescence immunoassay method type	Enzyme-linked immunosorbent assay method type
Detection system	Flow through electrochemiluminescence detection cell	Flow through cuvette with halogen lamp light source
Sample positions	30 positions for samples, controls and calibrators	150 positions for samples, controls and calibrators
Sample volume / test	10 to 50µL	5 to 200 µL
Reagent positions	15 reagent positions 2 diluent/reagent positions 1 BlankCell position	12 reagent positions 1 cleaning solution 2 universal substrate

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510(k) Summary, Elecsys 2010® Analyzer Continued

6) Comparison to predicate device, (cont.)

Performance Characteristics:

Feature	Elecsys 2010 vs. ES300 Least Squares Regression
Method Comparison T4	Y = 1.02x +0.85 SEE = 5.39 r = 0.947
Method Comparison FT4	Y = 0.954X + 0.18 SEE + 1.11 r + 0.981
Method Comparison TSH	Y = 1.09X + 0.14 SEE = 0.798 r = 0.991; n = 132
Method Comparison T-Uptake	Y = 0.99X - 0.03 SEE = 0.04 r = 0.908; n = 319
Method Comparison hCG	Y = 1.35X - 9.21 SEE = 17.50 r = 0.989; n = 64
Method Comparison Troponin-T	Y = - 0.033 + 0.996 SEE = 0.547 r = 0.969; n = 54